

Application No. 10/720,213
Amendment dated January 12, 2011
Reply to Office Action of December 29, 2010

REMARKS

**Reconsideration And Allowance
Are Respectfully Requested.**

Claims 1, 2, 7 and 8 are currently pending. Claims 2, 7 and 8 have been amended. Claims 3, 4, 9 and 10 have been canceled by way of the present amendment. Claims 5 and 6 were previously canceled. No new matter has been added. No new claims have been added. Reconsideration is respectfully requested.

Applicants would first like to thank Primary Examiner Mendez for the courtesies extended during the Interview conducted on October 15, 2010. During the course of this Interview, the pending claims were discussed in conjunction with the previously cited references and newly discovered U.S. Patent No. 4,813,422 to Fisher et al. ("Fisher"). Based upon the discovery of Fisher, it was agreed the Examiner would prepare a new Office Action in view of the new prior art presented by Applicants' representative. Accordingly, a new Office Action has been issued.

In accordance with the outstanding Office Action, claims 1-4 and 7-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,547,187 to Kelly ("Kelly") in view of Fisher, U.S. Patent No. 6,811,559 to Thornton ("Thornton"), U.S. Patent No. 6,682,508 to Meythaler et al. ("Meythaler"), or U.S. Patent No. 5,293,875 to Stone ("Stone"), and further in view of U.S. Patent No. 5,234,409 to Goldberg et al. ("Goldberg").

Application No. 10/720,213
Amendment dated January 12, 2011
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This rejection is respectfully traversed in view of the preceding amendments and the remarks which follow.

In particular, independent claims 1 and 7 have been substantially amended in an effort to overcome the cited references. Claim 1 now requires a single use catheter having a lumen with a proximate end with a hydrophilic filter tip. The lumen also includes a distal end. The single use catheter also includes an inflatable cuff surrounding the lumen. The lumen has a first conduit and a second conduit parallel to each other. The first conduit is in fluid communication with the inflatable cuff and the second conduit is in fluid communication with the proximate end of the lumen. A charcoal filter is positioned in the second conduit. A tube is positioned at an end of the first conduit. A one-way valve is positioned within the tube. The one-way valve completely controls a solution injected into the first conduit and allows inflation of the cuff but does not allow deflation. As such, the first conduit must be cut to deflate the cuff. The one-way valve controls the entire solution flow into the first conduit for inflation of the cuff.

Considering now the references cited in the outstanding Office Action, the primary reference of Kelly discloses basic structure but does not disclose either a hydrophilic filter tip at the proximal end of the lumen or a charcoal filter in the second conduit. The Office Action, however, cites Fisher, Thornton, Meythaler, Stone and Goldberg as teaching such features and suggests the modification of Kelly "would have been considered conventional in

Application No. 10/720,213
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the art at the time the invention was made as evidenced by the teaches of Fisher, Thornton, Meythaler, or Stone”.

An obviousness rejection is not predicated upon merely finding the claimed limitations in the cited references. Rather, there must be some reason for combining the references in a manner reading upon the pending claims.

As noted in the *Examination Guidelines Update; Developments in the Obviousness Inquire After KSR v Teleflex*, “even where a general method that could have been applied to make the claimed product was known and within the level of skill of the ordinary artisan, the claim may nevertheless be nonobvious if the problem which had suggested use of the method had been previously unknown”. *In re Omeprazole Patent Litigation*, 536 F.3d 1361 (Fed. Cir. 2008).

This case law is especially applicable to the present situation. Kelly discloses an inflatable cholangiocath and method for cholangiography. In particular, the device is designed for utilization in the treatment of gall stones and the inflatable cholangiocath provides a mechanism for exploring the common bile duct following surgery. One of ordinary skill in the art would, therefore, ask why a hydrophilic filter tip and a charcoal filter would be appropriate for utilization in conjunction with the procedure taught by Kelly. The answer ultimately is that there is no reason for incorporating these features into Kelly.

Application No. 10/720,213
Amendment dated January 12, 2011
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The cited references where hydrophilic filter tips and charcoal filters are employed relate to devices associated with bowel obstruction; Fisher discloses a "Bowel Control Probe and Method for Controlling Bowel Incontinence" and Goldberg discloses a "Female Incontinence Control Device and Method".

With regard to the other cited references, Thornton discloses an "Intravascular Device for Venting an Inflatable Chamber", Meythaler discloses a "Direct Central Nervous System Catheter and Temperature Control System" and Stone discloses a mechanism for "In-Vivo Measurement of End-Tidal Carbon Monoxide Concentration Apparatus and Methods".

None of these references contemplate or relate to the problems associated with the performance of a cholangiography as contemplated by Kelly. As such, any problems addressed by the cited teaching references are ultimately inapplicable to Kelly and the suggested rejection merely amounts to distinct disclosures of various elements with no real rationale for the combination. This is contrary to the teachings of *KSR* and it is Applicants' opinion the amendments to claim 1 overcome the cited references.

Accordingly, Applicants respectfully request the outstanding rejections be withdrawn and that the application be passed for allowance. As to those claims which depend from claim 1, they are also believed to overcome the cited references for at least the reasons discussed above, and Applicants respectfully request the rejection of these claims be withdrawn.

Application No. 10/720,213
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It is believed that this case is in condition for allowance and reconsideration thereof and early issuance is respectfully requested. If it is felt that an interview would expedite prosecution of this application, please do not hesitate to contact applicants' representative at the below number.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Stewart L. Gitler". The signature is fluid and cursive, with the first name "Stewart" and last name "Gitler" clearly distinguishable.

Stewart L. Gitler
Registration No. 31,256

Welsh Flaxman & Gitler LLC
2000 Duke Street, Suite 100
Alexandria, VA 22314
(703) 920-1122